5 steps to a smooth CE, UKCA and ISO 13485 certification transfer

Transferring your certification to BSI is simpler than you think. With global expertise and decades of experience, we make the process seamless and quick—so you can stay focused on what matters. **Here's how it works:**

1

STEP ONE

Understanding, planning, and documentation

Tell us your goals, challenges, and share your documentation. For legacy devices transitioning to MDR/IVDR, you can also transfer their applications with your previous certification body, and the associated appropriate surveillance under the Directives. BSI will craft a well-structured, easy-to-follow transfer plan for you.

MILESTONE 2

STEP TWO

Contract signing with BSI

Once you sign the written agreement, the wheels are set in motion for a smooth transfer. A BSI Scheme Manager will be assigned to guide you through the entire transfer journey.

3

STEP THREE

BSI due diligence

For majority of the MDR/IVDR/UKCA certified devices, we conduct short due diligence checks of PMS data to ensure that there are no safety concerns. We will contact and co-ordinate with the previous certification body to complete the necessary formalities such as the transfer agreements.

4

STEP FOUR

Final Review & Decision Making

At the conclusion of all the due diligence checks, a final recommendation for transfer will be put together by the BSI Scheme Manager which will be reviewed in the legislatively mandated decision making step.

MILESTONE 5

STEP FIVE

Certificate issuance

Receive your BSI issued certificates and start placing devices on the market with the BSI certification body number as per the agreed labelling transition plan.